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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/818,583	03/28/2001	Hiroshi Tonoike	OKA-0025	3656

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EXAMINER

KIM, YOUNG J

ART UNIT	PAPER NUMBER
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1637

15

DATE MAILED: 08/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/818,583

Applicant(s)

TONOIKE, HIROSHI

Examiner

Young J. Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7-10 is/are allowed.
- 6) ☐ Claim(s) 1-6, 11 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

This Office Action responds the Amendment received on May 21, 2003 (Paper No. 14).

Specification

The objection to the specification for failing to comply with the Sequence Rules for failing to identify the nucleotide sequences (on page 12) with their proper SEQ ID Numbers, made in the Office Action mailed on February 21, 2003 is withdrawn in view of the Amendment received on May 21, 2003, amending the specification to compliance.

Claim Rejections - 35 USC § 112

The rejection of claims 1-11 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, made in the Office Action mailed on February 21, 2003 is withdrawn in view of the Amendment received on May 21, 2003, amending the base claim 1.

Claim Rejections - 35 USC § 102 - maintained

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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The rejection of claims 1-6 and 11 under 35 U.S.C. 102(b) as being anticipated by Steiner et al. (Nucleic Acids Research, 1995, vol. 23, no. 13, pages 2569-2570), made in the Office Action mailed on February 21, 2003 is maintained for the reasons of record.

Applicants' arguments received on May 21, 2003 have been fully considered but they are not found persuasive.

Applicants' arguments are addressed in the order they were presented.

Applicants state that Steiner et al. reference discloses the addition of 400 ul of ROSE containing 1% sodium lauryl sarkosyl to a 100 ul human blood sample, and polyvinylpolypyrrolidone (PVPP) is added to the ground lyophilized tissue (page 6, Response), but fails to anticipate the claims because ROSE also includes additional compounds such as 1% PVPP. In other words, Applicants contend that the Steiner reference requires that the sample be placed to allow the tissues and PVPP to settle before aliquots of extracts are taken for amplification by PCR (page 6, Response).

This is not found persuasive because claim 1 recites that the homogenized sample consists *essentially of* the living body-derived sample and a surfactant. Such claim language, absent a specific definition set forth in the specification, based on a broadest reasonable interpretation (MPEP 904.01) allows for inclusion of other ingredients, such as PVPP. With respect to Applicants' argument regarding the sample be placed to allow the tissues and PVPP to settle before aliquots are taken for amplification by PCR, the argument is not found persuasive because whether the tissues and PVPP are allowed to settle or not, the sample as a whole is added to a PCR reaction. In other words, the sample does not go through any more purification

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steps or extraction steps, but added to the PCR reaction solution. Additionally, Steiner et al. discloses the advantage of their method:

“In our method, ROSE buffer is added to the ground samples, the tubes are capped and incubated and **no further transfer or addition steps are required**. The completely self-contained extraction environment also reduces the chances of cross-sample contamination” (page 2570, 2nd column).

The phrase, “no further transfer or addition steps are required,” refers to the steps which are required by the conventional extraction methods before storage or amplification by PCR (page 2570, 2nd column) - an advantage Steiner et al. explicitly state. Therefore, based on this context, it is clear that the method disclosed by Steiner et al. anticipates the invention as claimed.

The rejection of claim 12 under 35 U.S.C. 102(b) as being anticipated by Liu et al. (Di San Junyi Daxue Xuebao, 1999, vol. 21, no. 1, Abstract only), made in the Office Action mailed on February 21, 2003 is maintained for the reasons of record.

Applicants’ arguments received on May 21, 2003 have been fully considered but they are not found persuasive.

It appears that Applicants’ only argument regarding this rejection is based on the fact that, “Liu does not disclose, teach or suggest that the **anionic surfactant**” (page 8, Response; emphasis added) be used for storage.

Claim 12 is not drawn to the use of an anionic surfactant, but any surfactant.

As already set forth in the previous Office Action, SDS used by Liu et al. is considered to be a surfactant, rendering the claims clearly anticipated.

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Therefore, Liu et al. anticipates the invention as claimed.

Conclusion

Claims 1-6, 11, and 12 stand rejected.

Claims 7-10 stand allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Inquiries

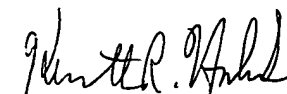
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (703) 308-9348. The Examiner can normally be reached from 8:30 a.m. to 7:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (703)-308-3905. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant

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or applicant's representative. **NO DUPLICATE COPIES SHOULD BE SUBMITTED**, so as to avoid the processing of duplicate papers in the Office. The Fax number is (703) 746-3172. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Young J. Kim

7/31/03



KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

8/4/03